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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,765	01/29/2002	Nobuyuki Itoh	201130.408D1	9697

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/060,765	ITOH ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed on 04/22/2005 has been entered in full. The affidavit of Dr. Michael Kavanaugh under 37 C.F.R. 1.131 accompanying Applicants' response has also been entered. Claims 15-18 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The rejection of claims 15-18 under 35 U.S.C. 102(e) as being anticipated by Agarwal et al. (US20010012628A1, Publication Date: August 9, 2001; earliest priority date: November 5, 1999), as set forth at pages 2-3 of the previous office action (Paper No. 01282005, mailed date: 01/31/2005), has been withdrawn in view of the affidavit of Dr. Michael Kavanaugh under 37 C.F.R. 1.131. .

Claim Rejections under Double Patenting

(i). A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

(ii). Claim 15-18 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 15-18 of copending Application No. 10/771, 173. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections—35 USC §112, 1st paragraph

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 15-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO: 4 and an epitope-bearing portion of the polypeptide of SEQ ID NO: 4 that serves as an antigenic determinant for production of an antibody that binds to the polypeptide of SEQ ID NO: 4, does not reasonably provide enablement for the genus of epitopes of SEQ ID NO: 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the

amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

The breadth of the claims. Claims 15 has the broadest scope and is drawn to an epitope-bearing portion of SEQ ID NO: 4, whereas claim 15 is drawn to an epitope-bearing portion of SEQ ID NO: 4 comprises between 10 and 50 contiguous amino acids of SEQ ID NO: 4. Thus, claims 15 and 16 do not recite any specific functional limitation or particular conserved structure. Claims 17 and 18 recite an epitope comprising a specific amino acid sequence. Yet claims 17 and 18 still do not recite any functional limitation, for example, the epitope is useful for producing an antibody that binds to the polypeptide of SEQ ID NO: 4. Therefore, the claims are broad and encompass a genus of epitopes comprising as few as 3 amino acids (see bottom of page 25 of the specification for the definition of epitope).

Nature of the invention and the state of the prior art. The present invention is related to the polypeptide of SEQ ID NO: 4, which belongs to the fibroblast growth factor (FGF) family. Numerous FGFs are known in the art, including the FGF polypeptide taught by Agarwal et al. (US20010012628A1, Publication Date: August 9, 2001; earliest priority date: November 5, 1999), which is shares 99.4% amino acid sequence identity

with SEQ ID NO: 4. The biological functions or properties of members of the fibroblast growth factor family are very divergent. For example, FGF-1 and FGF-2 are potent mitogens for a variety of cell types; the gene encoding FGF-3 is a common target for activation by the mouse mammary tumor virus whereas the genes encoding FGF-4, FGF-5, and FGF-6 have transforming activity when introduced into NIH 3T3 cells. FGF-7, FGF-8, and FGF-9 are mitogens for ketatinocytes, mammary carcinoma cells, and astrocytes, respectively (Smallwood et al, *Proc. Natl. Acad. Sci. USA* 93:9850-9857, 1996. See page 9850, 1st paragraph of left column). Despite the fact that numerous FGFs were discovered, as noted above, there were no sufficient teachings on how to make and/or use the majority of the species encompassed in the claimed genus. It is routine for an artisan to produce an antibody with an epitope of a polypeptide. However, such an antibody may also bind to a homologue of the polypeptide or even an entirely different polypeptide.

The amount of direction or guidance presented and the existence of working examples. Despite the fact that the instant disclosure provides sufficient guidance on how to make and use the polypeptide set forth in SEQ ID NO: 4 and an epitope comprising SEQ ID NO: 7 or SEQ ID NO: 8 that is used for production an antibody that binds to the polypeptide of SEQ ID NO: 4, the instant disclosure fails to provide sufficient guidance/direction or working examples on the structural and functional requirements commensurate in scope with what is encompassed by the instant claims since the general disclosure that one could make and use SEQ ID NO: 4 or an epitope

comprising SEQ ID NO: 7 or SEQ ID NO: 8 could not be used to be such guidance as to guide one skilled in the art to make and use the genus of epitopes of SEQ ID NO:4 that comprise 3 or more amino acids of SEQ ID NO: 4. While an epitope or a fragment of the polypeptide of SEQ ID NO: 4 can be used for preparing an antibody, such an antibody does not necessarily bind to the full length polypeptide of SEQ ID NO: 4; and there is no requirement in the claims that the antibody produced by an epitope-bearing fragment bind the polypeptide of SEQ ID NO: 4.

The relative skill of those in the art, the predictability or unpredictability of the art, and the quantity of experimentation necessary. Although one skilled in the art certainly has the technology and skills to make and use any polypeptides with a defined amino acid sequence and a defined biological activity, it is unpredictable whether an antibody produced using an epitope-bearing portion of SEQ ID NO: 4 binds to the full length of SEQ ID NO: 4. Thus, it would take undue experimentation for one skilled in the art to make and/or use the claimed genus of epitopes.

Accordingly, while being enabling for the polypeptide of SEQ ID NO: 4 and an epitope-bearing portion of the polypeptide of SEQ ID NO: 4 that is useful for production of an antibody that binds to the polypeptide of SEQ ID NO: 4, does not reasonably provide enablement for the genus of epitopes of SEQ ID NO: 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

(iii). Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claims 15 is drawn to an epitope-bearing portion of SEQ ID NO: 4, whereas claim 15 is drawn to an epitope-bearing portion of SEQ ID NO: 4 comprises between 10 and 50 contiguous amino acids of SEQ ID NO: 4. Thus, the claims do not require that the epitope possesses any biological activity, nor any particular conserved structure, or other disclosed distinguishing feature.

The instant disclosure of two FGF polypeptides, human FGF polypeptide of SEQ ID NO: 4 and mouse FGF polypeptide of SEQ ID NO: 2, and their encoding nucleic acids, as well as two epitope fragments consisting of 15 and 16 contiguous amino acids of SEQ ID NO: 4, does not adequately support the scope of the claimed genus. A description of

a genus of polypeptides may be achieved by means of a recitation of a representative number of the polypeptides, defined by amino acid sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. However, the instant disclosure fails to provide sufficient description information, such as definitive structural or functional features of the claimed genus of polypeptide. Other than the polypeptide of SEQ ID NO: 4 and two disclosed epitopes of SEQ ID NOS: 7 and 8, there is no sufficient description on the genus of epitopes in view of the broad definition of "epitope" (bottom of page 25 of the specification). Furthermore, the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed polypeptide as being identical to those instantly claimed.

Due to the breadth of the claim genus and lack of sufficient recitation of distinguishing identifying characteristics, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus. Therefore, only isolated polypeptide of SEQ ID NO: 4 and an epitope comprising SEQ ID NO: 7 or 8, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph.

It is noted that claims 15 and 16 were rejected under 35 U.S.C.112, 1st paragraph for scope of enablement and written description in Paper No. 05172004 (mailed on 05/25/2004) and the rejections were withdrawn in Paper No. 01282005 (mailed on

01/31/2005). In this office action, on further consideration, all the pending claims, which are drawn to epitopes of SEQ ID NO: 4, are rejected under 35 U.S.C.112, 1st paragraph. Applicants argued, in the reply filed on 11/19/2004, that the instant disclosure and the teachings in the art provide sufficient description, guidance and direction on how to make and use the invention. This is not persuasive for the reasons set forth in the new rejection above.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li, Ph.D.
Examiner
July 14, 2005